

Clinical trial of a low-cost, high power compression hearing aid.

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Introduction:

In July 2001 the WHO-programme for Prevention of Blindness and Deafness launched its: "*Guidelines for Hearing Aids and Services for Developing countries*". The guidelines were developed by an expert group recommending minimum requirements for the technical performance of the aid, the ear-mould and especially the services for providing hearing aids (HAs) to the consumers regarded as an essential component of

a hearing health system (1). Succeeding the launch of the guidelines, a field test was performed of a low cost solar powered hearing aid (HA) at a cost of 50 Euro targeted to subjects with moderate hearing impairment. Apart from minor technical insufficiencies related to the assembly of the HA, the amplification in the low frequencies was compatible with hearing losses of up to 60 to 70 dB, whereas the amplification in the high frequencies did not reach the target as recommended by the NAL-R prescription (2). Subjective assessment of the aid using the IOI-HA (3,4) showed “high satisfaction” with the aids and a reduction in the activity limitations resulting from the subjects’ hearing impairment. (5).

It is estimated that 250 mill. people suffer from disabling hearing impairment and 2/3 of these are living in the developing world (1). Current available HAs with DSP-technology cannot be afforded in the developing world both due to the necessary computerized fitting equipment, the high professional qualifications demanded for the fitting - which are not available - and the price of the device. However to meet the great needs for HAs in the developing world some manufacturers assemble the necessary technical components from traditional HAs, but also these aids need a clinical test after production as part of quality control.

Thus this contribution reports the results of a clinical trial of a low-cost high power compression behind- the- ear hearing aid (BTE-HA) produced by Godisa in Botswana, hereafter named the test-HA. The battery of the HA can be powered from a solar power charger but has in this context been powered by an ordinary air-zink battery type 13 (Varta), offered free of charge to the subject.

Material:

Among persons fitted with HAs in the clinic at least 6 months before the trial with the test-HA - thus being experienced HA user - were drawn from the department’ computerized files. The following inclusion criteria were used: the person should be mentally intact, have a hearing threshold equal to or greater than 50 dB HL at 2 kHz, be fitted bilaterally- preferably with BTE-HAs-, be mobile and voluntarily consent to participate in the project based on written and oral information. N=117 were contacted, however only N=21 could be recruited, 14 males and 7 females at a median age at 77 years range 50-86. Due to the difficulties in recruiting subjects to participate in the trial the original inclusion criteria had to be softened and thus 4 subjects who had been fitted monaurally were accepted, among these two with unilateral deafness.

N= 18 subjects had pure sensorineural HI whereas N=3 had a mixed conductive/ sensorineural HI. In fig 1 is shown the median hearing thresholds and range in the N= 38 HA fitted ears. All subjects had been examined following the normal routine of the department (6) using equipment and procedures recommended according to ISO-8253 part 1-3(7), ISO 389-3 (8) and ISO-7566 (9).

It should be mentioned that all fittings are performed with the individual ear mould without ventilation canal due to the severe HI according to the recommendations of Sullivan (10).

Procedure:

Fitting of the test-HA was based on the NAL-R prescription rule (2) or the POGO-rule (11) depending on the degree of the subject's HI and all the fittings were validated by insertion gain measurements, using a Siemens Unity-IG equipment. The immediate benefit of the test-HA was measured by the difference in speech recognition scores without and with the test-HA in quiet (SRS) and in background noise (S/N=5 dB) (SRSN). After a 6-8 weeks trial period the person met for follow-up and completion of a structured interview based on the IOI-HA (3,4). The IOI-HA form includes 7 questions with responses according to a graded scale 1-5, where 5 is the maximum score. A previous factor analysis has shown that questions 1+2+4+7 relate to "satisfaction", while questions 3+5+6 relate to limitations in activities (appendix 1). At the end of the session the subject should make a preference for the test-HA or the previously fitted HA named HA-AA.

In order to compare the test HAs with the HA-AA, the SRS and SRSN had been measured with the AA-HA just before the fitting of the test-HA at the first session, but for various reasons a IOI-HA related to the AA-HA was not completed at this session. Those who at the end of the trial preferred the AA-HA for the test-HA completed the IOI-HA referring to their preference and mailed their responses to the department.

In N= 17 the HA-AAs were DSP-HAs, whereas N=4 had been fitted with analogue HAs.

Data-analysis:

The immediate HA-benefit of the test-HA was given as the difference in SRS and SRSN without and with the HA. The SRS and SRSN with the HA-AA were compared with the corresponding result of the test- HAs. The outcome of the IOI-HA questionnaire completed at the follow-up is indicated as the median value for each response respectively and for the median of the total score. For those responding to the IOI-HA by mail referring to the HA-AA the median score was evaluated and compared to the IOI-scores of the test-HA.

For statistical analysis was used Wilcoxon's non- parametric rank sum test for paired data with a significance level of 5%.

Results:

Fig.2 shows the results of the insertion gain (IG) measurements obtained with the test-HA at the fitting. It is obvious that the test-HA meets the frequency and amplification characteristics required by the NAL-R-prescription rule. Noteworthy is the amplification in the high frequencies being important for the speech recognition, especially in background noise compatible with the prescription.

The median SRS without HA was 12% (range 0-88) and improved to median 78% (range 8-100) with the test-HA. The SRSN without HA was 6% (range 0-76) and improved to median 60% (0-88) showing a statistically improved benefit on a group basis with the test-HA in both the situation in quiet and in noise (S/N=5 dB). The immediate benefit analysed on an individual basis showed an improvement of median 52% (range 8-96) in quiet and of median 43% (range 0-76) in background noise (S/N=5%) with the test-HA.

The SRS with the AA-HA was median 72% (range 16-100) and the SRSN was 68% (range 0-96) on a group basis, while the individual benefit was median 54% (range 8-96) in quiet and median 44% (0-84) in background noise (S/N= 5 dB). Thus no statistical differences in the speech recognition scores either in quiet or in background noise was found when comparing the results to the test-HA with the AA-HA.

The median frequency and amplification response obtained with the HA-AA is shown in fig. 3, fitted according to the prescription algorithm of the various manufacturers.

The score of the IOI-HA for the test-HA was ranging from median 3-5, with a total median score of 3,9 (range 2,6-4,7). In table 1 is shown the median score for each item and the range with the test-HA.

At the follow-up session the subject could make a preference for the test-HA or the HA-AA. N= 15 preferred the AA-HAs, whereas N=6 preferred the test-HAs and thus were provided with these aids replacing the aids originally fitted in the department.

N=13 responded to the IOI-HA referring to the AA-HA showing median total score of 3,7 (2,9-4,6. Due to the lack of information from 7 subjects concerning the IOI-HA related to the AA-HA a comparison between the IOI-HA for the test-HA and AA-HA cannot be made.

Technical evaluation:

In contrast to the former HAs tested targeted to moderate hearing impairment, the manufacture of the present low-cost HAs was perfect, and will not allow moist and dirt to enter the aid. Thus the mechanical precision has been improved substantially. In fig 4 is shown the typical acoustic characteristics related to frequency and output measured in a 2 cc coupler at 60 dB SPL (N=?)

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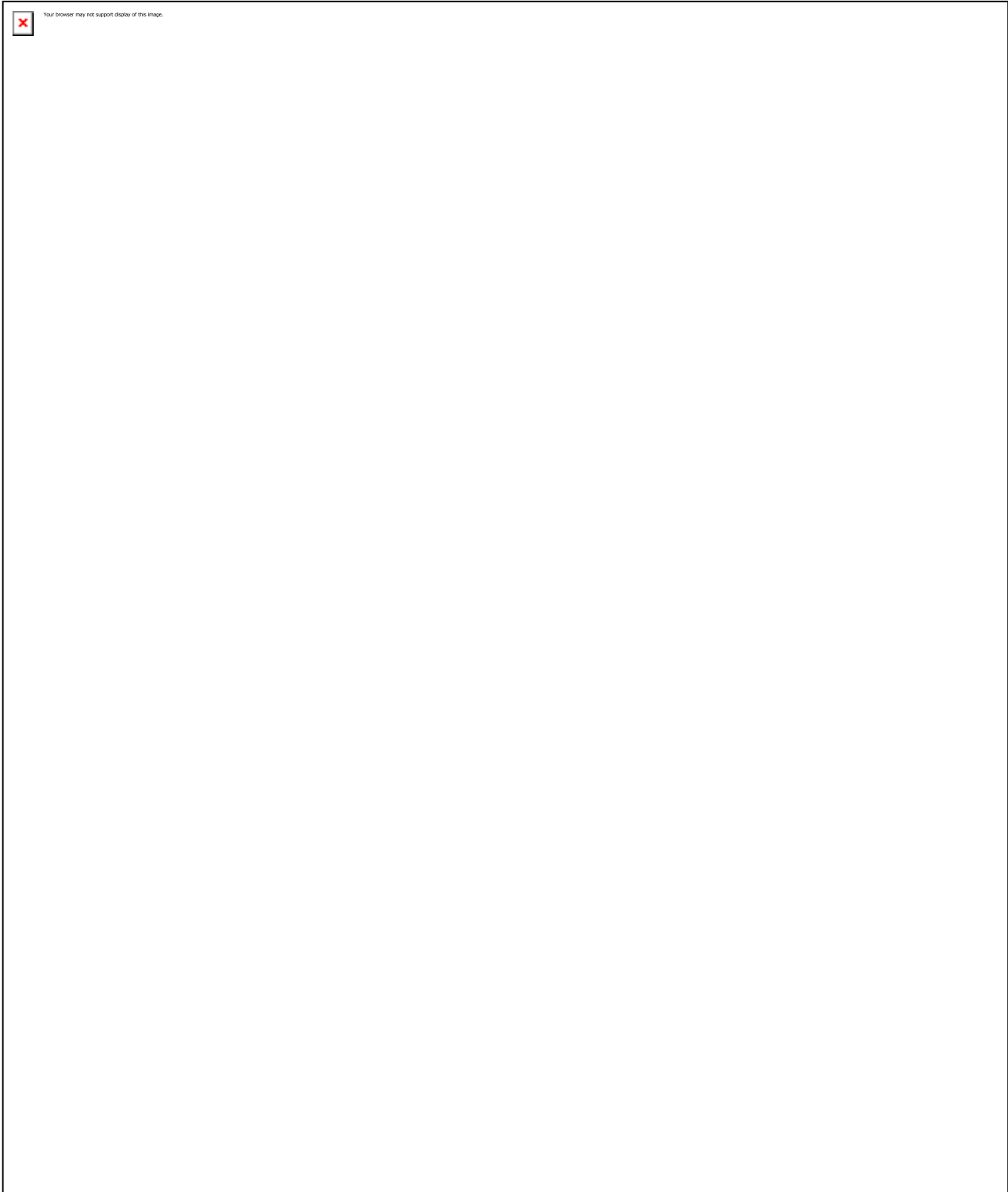
Comments:

The present trial shows that: the tested low-cost HA results in “benefit” both by subjective and objective measures; that it gives a “benefit” similar to current available modern HAs and that the technical characteristics meet the requirements as described in the guidelines from WHO (1). It should however be noted that the design of this trial, the number of subjects included and the selection bias in recruiting cannot allow any firm scientific comparisons. The trial shows that the quality of the test-HA meets the requirements for fitting HAs in both the developed and developing world.

The problems in recruiting subjects for the trial is unusual and although it was tried to avoid selection bias, it may be argued that those participating are especially eager to try any HA to alleviate their problems resulting from severe hearing impairment. Irrespective of this all were experienced HA-users and thus capable of making a valid preference for one of the aids. N=6 preferred the test-HA to their modern programmable or DSP-HA, supporting previous scientific reports showing that the advanced modern devices may not be superior to an analogue HA (12,13,14). Thus a “low-technology” HA can be fitted and result in benefit in both developed and developing countries. However the DSP-technology is more cost/effective for the industry and therefore it seems important that a production of analogue HAs is maintained in developing countries at a low cost. Thereby HAs can be affordable and available to the many hearing impaired people in the developing countries.

Conclusions:

On the basis of this clinical trial and the technical evaluation it can be concluded that the low-cost high powered compression HA offers substantial benefit to the hearing impaired with a severe predominantly sensorineural hearing impairment, i.e > 60 dB at 2 kHz. In addition the IG- measurements allow to conclude that the test-HA gives sufficient amplification according to the NAL-R prescription in the desired frequency range.



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